OSTEOSELECT® DEMINERALIZED BONE MATRIX PUTTY
OSTEOSELECT® *PLUS* DEMINERALIZED BONE MATRIX PUTTY
PACKAGE INSERT

STERILE R

READ BEFORE USING

DESCRIPTION

Both OsteoSelect® Demineralized Bone Matrix Putty (DBM) and OsteoSelect® *PLUS* DBM Putty are prepared from donated human tissue processed using aseptic surgical techniques. These bone void fillers are a combination of human demineralized bone matrix (DBM) and a biocompatible and bioabsorbable carrier, carboxymethylcellulose, mixed into a putty-like consistency for ease of surgical use. OsteoSelect® DBM Putty is processed using fine particles of bone and OsteoSelect® *PLUS* DBM Putty contains a mixture of fine particles and larger granules.

Tissue is first disinfected and then terminally sterilized in the final package using low-dose gamma radiation to provide a SAL of 10^{-6}. The material may contain traces of the processing reagents Gentamicin, PVP-Iodine, alcohol and surfactants. As a biological material, some variations in the product should be expected, such as in appearance and in handling.

OSTEOINDUCTIVITY POTENTIAL

OsteoSelect® DBM Putty and OsteoSelect® *PLUS* DBM Putty are osteoconductive and have been shown to have osteoinductive potential in an athymic rat model. It is manufactured via a processing method that has been validated to consistently produce DBM that is osteoinductive in an athymic rat assay. Product and process consistency are confirmed via ongoing testing of OsteoSelect® DBM Putty and OsteoSelect® *PLUS* DBM Putty finished product for osteoinductivity in a validated athymic rat assay. It is unknown how the osteoinductivity potential in the rat model correlates with human clinical performance.

DONOR SCREENING AND TESTING

The donor from whom this allograft was derived has been tested and found negative for the following:

HBsAg (Hepatitis B Surface Antigen), HBcAb (Hepatitis B Core Total Antibody), HBV-NAT (Hepatitis B Nucleic Acid Test), HCV (Hepatitis C Antibody), HIV 1/2-Ab (Antibody to Human Immunodeficiency Virus Types 1 and 2), Syphilis detection test, HIV-1 NAT (HIV-1 Nucleic Acid Test), and HCV NAT (HCV Nucleic Acid Test).

The donor was also tested for HTLV I/II (Human T lymphotrophic Virus Types I and II) and the results were found to be acceptable. Note: HTLV I/II testing is not currently a required test. If a donor was NOT tested for HTLV I/II the donor will be statused as a USA-only donor.

Additional RCDAD Donor Screening Tests Attached in this Space.

If additional donor screening tests for RCDADs are not listed in this space there were none performed.

Additional donor screening tests may have been performed on the donor. If additional tests for Human Immunodeficiency Virus, Hepatitis C or Syphilis were performed the results were reviewed and found to be **NEGATIVE**. Additional tests for other communicable diseases, such as West Nile Virus, *T. Cruzi*, Cytomegalovirus and Epstein Barr Virus may have been performed. The results of all additional communicable disease tests have been evaluated by the Medical Director and have been found acceptable according to regulations, standards and Bacterin policies and procedures.

If additional screening tests were performed for relevant communicable disease agents and diseases (RCDADs) as defined by the US FDA, they will be listed along with results in the box labeled “Additional RCDAD Donor Screening Tests Attached In This Space”. Donor screening tests are performed by laboratories registered with FDA to perform donor testing using FDA-licensed tests, when available, and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493.

The donor was selected based on results of the donor screening tests, review of the donor’s medical history, social history, external exam and relevant medical records available at the time of recovery which may include previous medical history, laboratory test results, autopsy and coroner reports (if performed), and information obtained from any source or records which may pertain to donor eligiblility. Such records have been evaluated by Bacterin’s Medical Director and are sufficient to indicate that donor eligibility criteria in place at the time of procurement have been met. This tissue is eligible for transplantation.

The names and addresses of the testing laboratories, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the eligiblity of this human tissue are on file at Bacterin and are available upon request. The criteria used for donor selection are in accordance with current policies and procedures approved by Bacterin. Policies and procedures for donor screening, serologic and microbiologic testing meet current standards established by the American Association of Tissue Banks, current United States Public Health Services Recommendations and FDA Federal Regulations and Guidance Documents.

INDICATIONS AND USAGE

OsteoSelect® DBM Putty and OsteoSelect® *PLUS* DBM Putty is indicated for use as a bone void filler and bone graft substitute for voids or gaps that are not intrinsic to the stability of the treatment site. OsteoSelect® (DBM) Putty and OsteoSelect® *PLUS* DBM Putty is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone.OsteoSelect® DBM Putty and OsteoSelect® *PLUS* DBM Putty can be used as follows:

- Extremities
- Pelvis
- Posterolateral spine

A US flag on the packaging of the graft indicates the graft is only approved for distribution and use in the United States of America.

CONTRAINDICATIONS / PRECAUTIONS

The allograft should not be used if the expiration date has been surpassed, the container in which the product is stored is damaged, the product is not labeled, or the required storage conditions have not been maintained. Caution should be exercised if the patient is allergic to any of the antibiotics or chemicals listed in processing and testing. The presence of infection at the transplantation site is a contraindication for the use of this allograft.

OsteoSelect® DBM Putty and OsteoSelect® *PLUS* DBM Putty is contraindicated where the device is intended for structural support in load-bearing bone and in articulating surfaces. Relative contraindications include the following:

- Severe vascular or neurological diseases
- Fever
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Hypercalcemia
- Renal impairment
- Active or latent infection
- History of, or active Pott’s disease
- Osteomyelitis or sepsis at the surgical site
- Hypercalcemia
- Inability to co-operate or comprehend post-operative instructions

ADVERSE EFFECTS

Possible adverse effects of using OsteoSelect® DBM Putty and OsteoSelect® *PLUS* DBM Putty include, but are not limited to:

- Infection of soft tissue and/or bone (osteomyelitis)
- Fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Hypercalcemia or transient hypercalcemia
- Fracture of the newly formed bone
- Disease transmission and undesirable immune response. Extensive screening procedures have been used in the selection of tissue donors. In spite of this careful donor selection and serological testing, transmission of infectious diseases such as HIV or hepatitis could occur.

Any Transmission Of Disease That Is Suspected To Be Caused By OsteoSelect® DBM Putty Or OsteoSelect® *PLUS* DBM Putty Or Any Other Adverse Outcome Potentially Attributed To This Graft Must Be Reported Promptly To Bacterin.

INSTRUCTIONS FOR USE

Caution: OsteoSelect® DBM Putty and OsteoSelect® *PLUS* DBM Putty Is Provided Sterile. DO NOT RESTERILIZE.

1. OsteoSelect® DBM Putty and OsteoSelect® *PLUS* DBM Putty packaging consists of the following: a) Outer Pouch (non-sterile); b) Inner Foil Pouch (sterile); and c) Sealed Jar or Capped Syringe (sterile).
2. Examine the outer pouch for integrity. Do not use if there is evidence that the outer pouch is damaged or sterility has been compromised, or if the product label or identifying bar code is severely damaged, illegible or missing. Confirm that the expiration date shown on the label has not passed.
3. Utilizing aseptic technique, the non-sterile team member should peel open the outer pouch and deliver the inner foil pouch containing the sealed jar or capped syringe to the sterile field or sterile team member.
   - Once the container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.
4. The sterile team member should examine the inner foil pouch to ensure it is intact. The putty should not be used if damage is noted.
5. Peel open the inner foil pouch and remove the sealed jar or capped syringe.
6. Twist off jar lid or syringe cap
7. Remove putty or push on plunger to extrude putty for use.
8. Discard any unused portion.
9. Apply and use the OsteoSelect® DBM Putty or OsteoSelect® *PLUS* DBM Putty as per established surgical technique and surgeon's preference.

Caution: This Allograft Material Is Intended For Single-Patient Use, On A Single Occasion Only. Discard Any Unused Material After The Package Has Been Opened.

Caution: Human tissue for transplantation shall not be offered, distributed or dispensed for veterinarian use.

VIRAL INACTIVATION AND CLEARANCE

The process used to make Demineralized Bone Matrix for OsteoSelect® DBM Putty and OsteoSelect® *PLUS* DBM Putty was validated for its ability to inactivate and/or clear a panel of model human enveloped and non-enveloped viruses representing DNA- and RNA-containing viruses and various viral shapes and sizes. This testing demonstrated the process provides suitable viral inactivation potential for a wide spectrum of potential human viruses. This inactivation potential provides additional viral contamination risk reduction beyond that provided through donor screening.

TISSUE TRACKING

OsteoSelect® DBM Putty is packaged in sterile, single-patient-use containers and the Unique Graft Serial Number, expiration date, product code, size, and additional information are listed on the package label.
Extra labels have been included with this graft for use by the end-user.
The Hospital must maintain records so that possible infections or other adverse reactions associated with this product can be linked back to the original source. It is the responsibility of the user surgeon to complete recipient records for the purpose of tracking tissue post transplant. Complete the enclosed Transplant Utilization Record in detail and return as indicated. If the graft is not used for any reason after opening, complete the enclosed Transplant Utilization Record in detail, noting the method of disposal, and return as indicated. Copies of this information should be retained by the transplant facility for future reference.

STORAGE

It is the responsibility of the Tissue Dispensing Service and/or end-user clinician or facility to maintain this product in appropriate storage conditions prior to transplantation.

OsteoSelect® DBM Putty and OsteoSelect® *PLUS* DBM Putty - Store at 15°C to 30°C. Do not freeze or expose to extreme heat.

RETURNS

If for any reason tissue must be returned, a return authorization is required from Bacterin prior to shipping.

Caution: Federal (US) Law Restricts This Device To Sale, Distribution And Use By Or On The Order Of A Physician.

OsteoSelect® is a trademark of Bacterin.

Bacterin Corporate Office: 664 Cruiser Lane, Belgrade, MT 59714

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